



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Washington, DC 20204

NOV 18 1998

3380 '98 NOV 25 P2:23

Pablo S. Quesada, Esq.  
Zack Kosnitzky  
NationsBank Tower  
100 Southeast 2nd Street  
Suite 2800  
Miami, Florida 33131-2144

Dear Mr. Quesada:

This is in response to your letter of November 11, 1998, on behalf of Catalysis S.L. of Madrid, Spain, to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that Catalysis S.L. is making the following statement, among others, for the product:

**VIUSID**

"...increase of the immunological [sic] defenses in all those processes that cause immunodeficiency [sic]"

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statement that you are making for this product suggests that it is intended to treat, prevent, mitigate, or cure disease, namely, immunodeficiency diseases. This claim does not meet the requirements of 21 U.S.C. 343(r)(6). This claim suggests that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

Please contact us if we may be of further assistance.

Sincerely,

Lynn A. Larsen, Ph.D.  
Director  
Division of Programs and Enforcement Policy  
Office of Special Nutritionals  
Center for Food Safety  
and Applied Nutrition

975-0163

LET 239

Page 2 - Pablos S. Quesada, Esq.

Copy: Josette Decaus  
General Manager  
Catalysis S.L.  
Zurbano, 39  
PO Box 19004  
28028 Madrid, Spain

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300  
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of  
Enforcement, HFC-200  
FDA, Florida District Office, Office of Compliance, HFR-SE240

cc:

HFA-224 (w/incoming)  
HFA-305 (docket 97S-0163)  
HFS-22 (CCO)  
HFS-456 (file)  
HFS-450 (r/f, file)  
HFD-310 (BWilliams)  
HFD-314 (Aronson)  
HFS-600 (Reynolds)  
HFS-605 (Bowers)  
GCF-1 (Nickerson, Dorsey)  
f/t:HFS-456:rjm:11/17/98:docname:62289.adv:disc33

**ZACK  
KOSNITZKY**  
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OF COUNSEL  
ARTHUR H. COURSHON  
MELVIN C. MORGENSTERN  
BYRON L. SPARBER  
SYDNEY S. TRAUM, P.A.

November 11, 1998

62284

Via Certified Mail,  
Return Receipt Requested

Office of Special Nutritionals  
HFS 450  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
200 C. Street, S.W.  
Washington, D.C. 20204

*Re: Notification Letter for Statements of Nutritional Support*

Dear Sir or Madam:

Our firm has been authorized by Catalysis, S.L. to represent it in all of its activities with the Food and Drug Administration including, but not limited to, filing its notification letters for statements of nutritional support.

Enclosed for your review and approval are notification letters executed by Catalysis, S.L. for its dietary supplements "VIUSID" and "KALSIS" which it intends to introduce in to the market in the coming months.

Thank you for your assistance on this matter. If you have any questions concerning the notification letters, please do not hesitate to contact me at (305) 536-6270.

Respectfully submitted,

*Pablo S. Quesada*

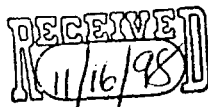
Pablo S. Quesada, Esq.

Enclosures



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HFS 450  
CENTER FOR FOOD SAFETY AND  
APPLIED NUTRITION  
200 C. STREET, S.W.  
WASHINGTON, D.C. 20204  
ESTADOS UNIDOS

Madrid, October 6, 1998

**Re: Notification Letter for Statements of Nutritional Support**

Dear Sir or Madam:

1.- **Statement of Purpose.** This notification letter is to provide notification of the following statements of nutritional support "VIUSID is a nutritional preparation specially designed for the increase of the immunological defenses in all those processes that cause immunodeficiency".

2.- **Vendor Information.** Manufacturer: CATALYSIS, S.L.  
Address: C/ Zurbano, 39  
28010 Madrid, Spain  
Telephone: +34 1 345 69 02

3.- **Product identification.** Trade name: VIUSID  
VIUSID is a dietary supplement made out of honey. The activation of the components of VIUSID increases to a great extent the power of the biological function of all of them, without modifying or changing the molecular structure.

4.- **Ingredient Statement.** Honey, Maleic Acid, Arginine, Glucosamine, Glycine, Ascorbic Acid, Pyridoxal, Folic Acid, Calcium Pantotenate, Zinc Sulfate, Cyanocobalamin, Lemon, Mint, Sodium Methylparaben, Sunett, Aspartame and Water.

5.- **Intended Use.** VIUSID is presented in flasks of 100 ml. The recommended dosage is one flask daily for adults and half a flask daily for children, taken in several doses during the day. The time of consumption can be prolonged according to the cases, since no contraindications have been detected.

6.- **Statements of Affirmation.** The information contained in this notice is complete and accurate and there is supporting evidence that the statement of nutritional support is truthful, nor misleading and scientifically valid. Moreover, the product does not present a significant or unreasonable risk of illness or injury under the conditions of use recommended or suggested in the labeling.

Respectfully submitted,

CATALYSIS, S.L.

JOSETTE DECAUX  
GENERAL MANAGER

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